

65. (Amended) A method for treating or preventing diabetes in a mammal, comprising administering insulin to a mammal having or at risk for developing diabetes in combination with a therapeutically effective amount of a protamine composition that comprises at least a first purified bioactive protamine in accordance with [any one of claims 1 through 13 or at least a first composition in accordance with any one of claims 14 through 31, 47 or 51] claim 1.

66. (Amended) The method of claim 64 [or 65], wherein said insulin and said protamine composition are administered to said mammal in a single pharmaceutical composition.

67. (Amended) The method of claim 64 [or 65], wherein said insulin and said protamine composition are administered to said mammal in distinct pharmaceutical compositions.

68. (Amended) The method of [any one of claims 56 through 67] claim 56, wherein said mammal is a human subject.

REMARKS

I. Nationalization

This application represents the U.S. national stage of International Patent Application PCT/US00/06876, filed March 15, 2000, which claims priority to U.S. provisional application Serial No. 60/124,873, filed March 17, 1999.

As the text of the International Application was filed with the U.S. receiving office, an additional copy is not required to satisfy 35 U.S.C. § 371(c)(2). International application PCT/US00/06876 was published as PCT Application WO 00/55196.

Should formal amendments be necessary to conform to U.S. practice, Applicants seek to introduce such amendments into the present specification by, *e.g.*, deleting the PCT cover page, providing the Abstract as a separate page, and deleting the PCT header.

Priority is also properly claimed by an amendment at page 1.

II. National Stage Claims

After according a U.S. filing date, and **before** calculating the filing fee, entry of the foregoing claim amendments is respectfully requested.

The changes to the claims are being made solely to conform to U.S. practice. All of the revised claims are fully supported by the specification and claims of the international and priority application and do not in any way constitute new matter. The submission of new claims does not represent abandonment of any of the subject matter of the claims in the international application.

III. Status of the Claims

Prior to entry into the national stage, claims 1-68 were pending. Presently, claims 9-13, 25-34, 47 and 51 have been canceled entirely without prejudice and without disclaimer. Claims 4, 14, 17-19, 22-24, 35, 37-46, 50, 52, 53, 55 and 57-68 have been amended to even further improve their clarity. No claims have been added.

Claims 1-8, 14-24, 35-46, 48-50 and 52-68 are therefore in the case. For the convenience of the Examiner, a copy of the pending claims showing the revisions is included herewith as **Exhibit A**. A clean copy of the pending claims is included herewith as **Exhibit B**.

IV. Support for the Claims

Aside from canceling the first and second medical use claims, not suitable for U.S. practice, revising the multiple dependencies throughout and introducing minor clarifying changes, the current claims represent those of the PCT application essentially in unamended form.

Most of the changes are designed to revise the multiple dependencies, so their support is clear within the claims themselves. Claim 30 has been revised to better match the preamble and the body of the claim. Claim 53 has been clarified to read in accordance with claim 18 ("further comprising at least one additional coagulant"). The change to claim 24 is additionally supported by the present specification at least at page 30, line 25.

It will therefore be understood that no new matter is encompassed by any of the amended or newly presented claims.

V. Fees and Formalities

The national filing fee and claim fees are included herewith. The fees have been calculated after the present changes to remove the multiple dependencies throughout the claims. Any omitted fees should be deducted from Williams, Morgan & Amerson Deposit Account No. 50-0786/4100.001400.

Applicants are entitled to small entity status and a properly executed declaration to this effect is enclosed.

Should the Examiner have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,



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